

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 4541-4560

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501 (c), the strength of the article differed from that which it purported and was represented to possess; and, Section 501 (d) (2), a substance had been substituted in whole or in part for the article.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4541. Alpha-estradiol tablets. (F. D. C. No. 33749. S. No. 23-101 L.)

INFORMATION FILED: 1-21-53, S. Dist. N. Y., against Cedardale Drug Co., Inc., New York, N. Y., and Sol Lederman, president and treasurer.

SHIPPED: 4-4-50, from New York to New Jersey.

CHARGE: 502 (b) (1) and (2)—the tablets failed to bear a label when shipped containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the tablets failed to bear a label containing the common or usual name of each active ingredient; and, 502 (f) (1)—the labeling of the tablets failed to bear adequate directions for use.

PLEA: Not guilty.

DISPOSITION: On 8-16-54, the case came on for trial before the court without a jury, and at the conclusion of the trial the court rendered a verdict of guilty. On 9-21-54, the court fined each defendant \$1,000.

4542. Pentobarbital sodium capsules. (F. D. C. No. 34854. S. Nos. 2-193/5 L.)

INFORMATION FILED: 7-22-53, E. Dist. Va., against Cradock Pharmacy, Inc., Cradock, Va.

SHIPPED: Between 12-17-51 and 1-3-52, from Virginia to Florida.

CHARGE: 502 (b) (1) and (2)—the article failed to bear a label when shipped containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (d)—the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and, 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

*See also No. 4560.

PLEA: Guilty.

DISPOSITION: 11-16-53. \$900 fine.

4543. B-amino-complex tablets. (F. D. C. No. 35676. S. No. 45-682 L.)

QUANTITY: 98 100-tablet btls. at Cambridge, Mass.

SHIPPED: 9-15-53 and 9-24-53, from New York, N. Y., by Unitone Corp.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label described in notice of judgment No. 4549.

LIBELED: 10-1-53, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use for the purpose for which it was intended, namely, in the treatment of deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 10-29-53 directing the removal of the libel action to the Eastern District of New York. On 2-1-55, with the consent of the claimant, Unitone Corp., a decree of condemnation and destruction was entered.

4544. Polyzone device. (F. D. C. No. 36465. S. No. 69-747 L.)

QUANTITY: 1 device at Pueblo, Colo.

SHIPPED: 6-16-53, from Los Angeles, Calif., by the Polyzone Co.

ACCOMPANYING LABELING: Leaflet entitled "For Doctors Only Polyzone."

RESULTS OF INVESTIGATION: The article was assumed to consist of a device for transforming ordinary diatomic oxygen into ozone (triatomic oxygen) for administration to the human body.

LIBELED: 3-26-54, Dist. Colo.

CHARGE: 502 (a)—the accompanying labeling of the device when shipped contained false and misleading representations that ozone produced by the device was nontoxic and that the device provided, through the agency of the ozone generated by it, an adequate and effective treatment for rheumatism, sciatica, heel spurs, arthritis, male and female pelvic infections, vaginal infections, rectal inflammations, infected rectal crypts, rectal tumors, rectal fissures, colitis, hemorrhoids, fistulas, pruritus ani, spastic sphincters, inflammations of the eye, ear, nose, and throat, sinus infections, internal and external ulcerations, and all acute and chronic conditions; and, 502 (f) (1)—the labeling of the device failed to bear adequate directions for use.

DISPOSITION: 11-4-54. Default—delivered to Food and Drug Administration.

4545. Polyzone device. (Inj. No. 284.)

COMPLAINT FOR INJUNCTION FILED: 10-22-54, S. Dist. Calif., against Roy G. Collison, t/a Polyzone Co., Los Angeles, Calif.

ACCOMPANYING LABELING: A leaflet entitled "For Doctors Only Polyzone" and a booklet entitled "Polyzone Therapy Manual."

RESULTS OF INVESTIGATION: The device was designed to produce ozone by the passage of oxygen through an electrical field.

CHARGE: That the defendant was causing the introduction into interstate commerce of the *Polyzone device*, which was misbranded under 502 (a) by reason of false and misleading representations, namely:

(1) That the ozone produced by the device was beneficial and useful for all acute and chronic conditions, arthritis, catarrhal deafness, fistulas,